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October 6, 2008

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RE:	Appellant:	LENEAU, Harry
	Serial No.:	10/629,880
	Filed:	July 29, 2003
	Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
	Art Unit:	1615
	Examiner:	SASAN, Aradhana
	Confirmation No.:	5579
	Our Docket:	P00903-US-01 (21934.0001)

APPELLANT'S REPLY BRIEF IN SUPPORT OF APPEAL FROM FINAL REJECTION TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

The Appellant has appealed to the Board of Patent Appeals and Interferences (the "Board") from the decision of Examiner Aradhana Sasan (the "Examiner") dated September 24, 2007 (the "Final Office Action"), the first Advisory Action Before the Filing of an Appeal Brief from Supervisory Patent Examiner Michael P. Woodward (the "Supervisory Examiner") dated January 30, 2008 (the "First Advisory Action"), and the second Advisory Action Before the Filing of an Appeal Brief from the Examiner dated March 31, 2008 (the "Second Advisory

Action"), finally rejecting claims 1, 3-10, and 13 of U.S. Patent Application Serial No. 10/629,880 (the "Application"). The Appellant filed a Notice of Appeal (the "Notice of Appeal") with the U.S. Patent and Trademark Office ("USPTO") on March 24, 2008, and a subsequent Appellant's Brief in Support of Appeal from Final Rejection to the Board of Patent Appeals and Interferences (the "Appeal Brief") on May 21, 2008, and that Appellant expressly does not waive any of its prior arguments by way of submission of the present Reply Brief.

In response to the Appeal Brief, Appellant received an Examiner's Answer from Examiner Sasan dated August 5, 2008. Appellant, within the two month reply deadline provided within 37 C.F.R. § 41.41, submits the present Appellant's Reply Brief in Support of Appeal from Final Rejection to the Board of Patent Appeals and Interferences (the "Reply Brief"). Appellant respectfully submits that the Reply Brief is not intended to be considered as a substitute brief replacing the original Appeal Brief filed on May 21, 2008.

Appellant does not believe that any payment of a fee is required for the submission of the present Reply Brief. In the event Appellant has inadvertently overlooked the need for an additional payment of a fee which may be required, Appellant conditionally petitions therefor, and authorizes any fee deficiency to be charged or any overpayment to be credited to deposit account 09-0007. When doing so, please reference docket number P00903-US-01 (21934.0001).

TABLE OF CONTENTS

STATUS OF CLAIMS

Claims 1-13 have been rejected under 35 U.S.C. § 102(e) pursuant to the Final Office Action." In response to the Final Office Action, Appellant filed a Response to Office Action (the "Response") on November 26, 2007, amending claim 12 to place it in independent form, cancelling claim 11 accordingly, providing comments in response to the 35 U.S.C. § 102(e) rejection contained within the Office Action, and requesting an Advisory Action. In response to the Response, the Supervisory Examiner mailed the First Advisory Action on January 30, 2008, rejecting the then-pending claims 1-10 and 12-13. In response to the First Advisory Action and a teleconference with the Supervisory Examiner on February 28, 2008, Appellant subsequently filed an Amendment After Final to Place the Application in a Condition for Allowance (the "Amendment After Final") on February 29, 2008, amending claims 1 and 13 and cancelling claims 2 and 12. As the Second Advisory Action was not mailed until March 31, 2008, Appellant filed the Notice of Appeal of March 24, 2008, to meet the statutory filing deadline. On March 31, 2008, and in response to the Amendment After Final, the Examiner mailed the Second Advisory Action, rejecting the then-pending claims 1, 3-10, and 13. Claims 1, 3-10, and 13 are presented for appeal. Claims 2, 11, and 12 have previously been cancelled. A copy of the presented claims was provided within the "Claims Appendix" (section VI) of the Appeal Brief. No additional claim amendments have been made by the Examiner or requested by Appellant.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner erred in rejecting claims 1, 3-10, and 13 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,924,273 to Pierce ("Pierce").

2. Whether the Examiner erred in considering the teaching cited by the Examiner as sufficient prior art under 35 U.S.C. § 102(e).

ARGUMENT

A. AS THE PIERCE PATENT CANNOT EFFECTIVELY CLAIM PRIORITY TO ITS UNDERLYING PROVISIONAL APPLICATION FOR SUPPORT OF AN ORAL COMPOSITION CONTAINING HYALURONIC ACID AS THE SOLE INGREDIENT, THE PIERCE PATENT DOES NOT SUFFICE AS PRIOR ART AGAINST THE PRESENT APPLICATION.

The provisional application for which Pierce claims priority did not properly and sufficiently enable an embodiment of the invention comprising hyaluronic acid and not glucosamine sulfate and chondroitin sulfate, and as such, Pierce does not suffice as prior art against the present application. As previously referenced with Appellant's Appeal Brief, on October 3, 2000, the attorney for Scott Pierce, John F. Dolan, filed U.S. Provisional Application No. 60/237,838, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'838 Application"). On October 2, 2001, another attorney for Scott Pierce, Isaac A. Angres, filed U.S. Non-provisional Patent Application No. 09/967,977, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'977 Application"), claiming priority back to U.S. Provisional Application No. 60/237,838. The '977 Application eventually issued as Pierce on August 2, 2005.

On May 18, 2001, the attorney for Appellant/inventor Harry Leneau, Jill Powlick of Barnes & Thornburg, filed U.S. Non-provisional Application No. 09/860,425, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'425 Application"). The '425 Application eventually issued as U.S. Patent No. 6,607,745 on August 19, 2003. Prior to the issuance of the '745 Patent, the same attorney for inventor Harry Leneau filed a continuation-in-part application on July 29, 2003, namely U.S. Non-provisional Application No. 10/629,880 (the present Application), entitled "INGESTION

OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'880 Application"). The '880 Application properly claimed priority back to the '425 Application. The '425 Application for which the present Application (the '880 Application) claims priority was filed after Mr. Pierce's provisional application (the '838 Application) but before Pierce's converted non-provisional application (the '977 Application, resulting in the Pierce patent).

Other than the brief statements referenced below by the Examiner within the provisional '838 Application where Mr. Pierce speculated that hyaluronic acid ("HA") itself would have the same alleged beneficial effects as the combination of HA, glucosamine sulfate ("GS") and chondroitin sulfate ("CS") together, Mr. Pierce's provisional '838 Application contains no effective support for an HA-only composition that would sufficiently enable one of skill in the art to conclude that such a composition containing HA as the sole "active" ingredient would benefit function as a chondroprotective / restorative agent like Chondrogen EQ as disclosed within Mr. Pierce's '838 Application.

B. THE PIERCE PATENT IS CLEARLY BROADER IN SCOPE THAN THE PIERCE PROVISIONAL APPLICATION, AS THE PIERCE PROVISIONAL APPLICATION DOES NOT DISCLOSE A SINGLE ORAL COMPOSITION CONTAINING HYALURONIC ACID AS THE SOLE ACTIVE INGREDIENT.

The Examiner improperly concluded that the scope of the '838 Application (Mr. Pierce's provisional application) was the same as the scope of the '977 Application (Mr. Pierce's non-provisional application) with respect to the alleged beneficial use of hyaluronic acid. In the Examiner's Answer, the Examiner stated that "Appellant argues that the "invention" of the '838 Application is clearly a composition containing glucosamine sulfate, chondroitin sulfate, and

hyaluronic acid, and not hyaluronic acid alone." Examiner's Answer, p. 3. In response, the Examiner stated the following:

> This is not found persuasive because the overall teaching of the Pierce patent (US 6,924,273) is the method of treating or preventing osteoarthritis, joint inflammation and pain by administering to a mammal hyaluronic acid (Col. 4, lines 46-55 and Col. 5, lines 30-35).
>
> Examiner's Answer, p. 3.

Within those two sections referenced by the Examiner, Pierce clearly states that "[t]he present invention provides a method for treating or preventing osteoarthritis ..., said method comprising orally administering to a mammalian species a therapeutically effective amount of hyaluronic acid or pharmaceutically acceptable salts thereof" (Pierce, col. 4, lines 46-55), and that "[t]he invention is also directed to a ... composition in paste form comprising ... an effective amount of Hyaluronic Acid ... and ... a sufficient amount of carboxymethylcellulose to make a paste" (Pierce, col. 5, lines 30-35). Appellant does not argue or contend that Pierce does not include the aforementioned statements. ***However, those disclosures within Pierce first appeared in Pierce's non-provisional patent application (the '977 Application), and that those statements do not have adequate support within the provisional application (the '838 Application) to which Pierce claims priority.*** Therefore, Mr. Pierce's non-provisional '977 Application cannot properly rely upon the filing date of the provisional '838 Application for priority, and in conclusion, ***neither*** of Mr. Pierce's applications are prior art to the present Application. The '425 Application, which the present Application (the '880 Application) properly claims priority, has an effective priority date earlier than Mr. Pierce's non-provisional '977 Application, and as the '838 Application provided no effective support for an HA-only

composition first introduced by Mr. Pierce within his non-provisional '977 Application, the '838 Application is also not prior art to the present Application.

In further support of the Examiner's position, the Examiner recognized Appellant's argument that "the '838 Application introduced, but did not enable, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate," whereby the Examiner disagreed and cited page 5, lines 5-11, of Pierce's provisional '838 Application in response. Examiner's Answer, p. 5. Those specific lines within the '838 Application read as follows:

> Another benefit received is that of oral preparation and administration of HA given, for example, in the equine in any formulation. The administration of the HA composition orally and having a clinical effect eliminates more evasive procedures. Other ways to give HA would be more invasive, such as injection by IV or other administration into the joints. Basically, embodiments of the present invention may include an oral preparation that is less invasive and also may include another embodiment which is the only oral way to give HA. This provides another alternative to giving it by an injection.
>
> '838 Application, page 5, lines 5-11.

This particular section of the provisional '838 Application is preceded by the following sentences ***within the same paragraph*** as referenced by the Examiner above, clearly demonstrating the context of the foregoing excerpt relates to a composition including HA, GS, and CS:

> There is a beneficial effect when Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid are administered orally. Generally, the oral administration of embodiments of the present application has a quicker clinical response than is produced when each component of the composition is given individually.
>
> '838 Application, page 4, line 20 to page 5, line 2.

In addition, the sentence immediately following the excerpt cited by the Examiner further clarifies the gist of Mr. Pierce's invention and the context of lines 5-11 as cited above:

> Another benefit is that ***embodiments of the present invention, with it's high dose of Glucosamine sulfate, Hyaluronic acid, and Chondroitin sulfate***, appears to have a synergistic effect which hastens the clinical response. (emphasis added)

'838 Application, page 5, lines 12-14.

Furthermore, it is clear that the aforementioned section within the '838 Application cited by the Examiner, while referring generally to an oral HA composition, ***does not in any way either (1) demonstrate that an oral HA preparation alone has any beneficial effects or (2) discuss what an oral HA preparation alone is even good for.*** Appellant notes the following individual sentences from the aforementioned section within the '838 Application cited by the Examiner:

1. "Another benefit received is that of oral preparation and administration of HA given, for example, in the equine in any formulation." Mr. Pierce makes this statement within the provisional '838 Application, but does not mention at all what the "benefit" is or recite any formulation whatsoever that contains HA as the sole "active" ingredient.

2. "The administration of the HA composition orally and having a clinical effect eliminates more evasive procedures." As with any drug, oral administration "eliminates more evasive procedures" such as injections. Mr. Pierce again does not describe what the "clinical effect" is for an HA-only formulation, and is actually referring to the "composition" that is a combination of HA, GS, and CS as previously discussed.

3. "Other ways to give HA would be more invasive, such as injection by IV or other administration into the joints." As mentioned above, it is inherently true that other ways of

ingesting ***any*** drug aside from oral administration "would be more invasive," but again, Mr. Pierce does not describe any benefit to an HA-only formulation.

4. "Basically, embodiments of the present invention may include an oral preparation that is less invasive and also may include another embodiment which is the only oral way to give HA." As referenced above, oral preparations of ***any*** drug are indeed less invasive than, for example, injections, and that Mr. Pierce, by stating "another embodiment which is the only oral way to give HA" has no support within the provisional '838 Application as he does not recite even one formulation containing HA as the sole active ingredient.

5. "This provides another alternative to giving it by an injection." Again, as referenced above, oral administration of ***any*** drug is indeed an alternative to giving it by an injection.

Notwithstanding the language from the Pierce provisional application cited out of context by the Examiner, the clear intent of Mr. Pierce within his provisional '838 Application was to describe his invention as being an oral embodiment of a product containing three active ingredients, namely HA, GS, and CS, and not any of these three ingredients alone.

C. THE PIERCE PROVISIONAL APPLICATION ONLY DISCLOSED TWO EMBODIMENTS OF CHONDROGEN EQ, WHICH CONTAINS HA, GS, AND CS, AND NOT ANY EMBODIMENTS OF AN ORAL COMPOSITION CONTAINING HA AS THE SOLE ACTIVE INGREDIENT.

Mr. Pierce's provisional '838 Application disclosed a composition called "Chondrogen EQ" which was allegedly "the most unique chondroprotective / restorative agent available." '838

Application, page 1. The '838 Application, as shown by numerous references therein, is very clear as to what the "invention" is within the '838 Application:

- "***The present invention***, which goes by the name Chondrogen EQ, was initially formulated ..." (emphasis added). '838 Application, page 1.

- "This highly palatable formulation is the first ***to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** in an easy to absorb, low molecular weight formula." (emphasis added) '838 Application, page 1.

- "***The present invention, with it's unique combination of GS, CS, and HA*** ..." (emphasis added). '838 Application, page 1.

- "As previously explained, ***the present invention comprises a highly palatable formulation, which is the first to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** ..." (emphasis added). '838 Application, page 3.

- "There is a beneficial effect when ***Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid*** are administered orally. Generally, the oral administration of embodiments ***of the present composition has a quicker clinical response than is produced when each component of the composition is given individually***." (emphasis added) '838 Application, pages 4-5.

- "Another benefit is that ***embodiments of the present invention, with it's high dose of Glucosamine sulfate, Hyaluronic acid, and Chondroitin sulfate***, appears to have a synergistic effect which hastens the clinical response." (emphasis added) '838 Application, page 5.

- "***One embodiment of the present invention is a unique formulation that combines Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid into a paste formulation*** ..." (emphasis added). '838 Application, page 5.

- "Early clinical trials have shown that ***when the three products are combined***, they have a synergistic effect." (emphasis added) '838 Application, pages 5-6.

- "***Embodiments of the present invention possess the following advantages***: ... 2) ***Only combination of GS, CS, HA in a paste formulation*** ..." (emphasis added). '838 Application, page 6.

- "Because of their chemical similarities and the clinical reports of improvement of synovitis, ***HA has a synergistic effect with GS and CS when given orally***." ..." (emphasis added). '838 Application, page 9.

As is shown by these statements within the '838 Application, it is clear that the "invention" of the '838 Application is a combination of HA, GS, and CS. In addition, and as referenced above, Mr. Pierce was also very clear in that the synergistic effect of HA, GS, and CS, and not any individual ingredient alone, was the emphasis of his invention disclosed within his provisional '838 Application. Additional support for this conclusion can be found ***in the only two exemplary formulations provided in the '838 Application***:

- Page 7: Embodiment comprising 46.03% Glucosamine sulfate, 4.60% Chondroitin sulfate, and 0.18% Sodium hyaluronate. In this embodiment, of the 50.81% (46.03% + 4.60% + 0.18%) combined active ingredients, only 0.35% (0.18%/50.81%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

- Page 11 (unnumbered – page appearing after numbered page 10): Chondrogen EQ formulation comprising 36% Glucosamine sulfate, 4% Chondroitin sulfate, and 0.144% Sodium hyaluronate. In this embodiment, of the 40.144% (36% + 4% + 0.144%) combined active ingredients, only 0.36% (0.144%/40.144%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

As is clearly shown, these two formulations only contain a very minor fraction of sodium hyaluronate (0.18% and 0.144%, respectively) as compared to the remaining ingredients. ***The provisional '838 Application of Mr. Pierce does not disclose a single formulation or embodiment of a oral product containing only HA without GS and CS,*** again noting that Mr. Pierce's provisional '838 Application is based upon Chondrogen EQ which contains HA, GS, and CS. When viewing the three named active ingredients of the "invention" of the '838 Application (namely HA, GS, and CS), sodium hyaluronate (the sodium salt of HA) only comprises 0.35% and 0.36%, respectively, of those two formulations. In the first formulation, for example, the

weight ratio to the largest active ingredient (GS) to sodium hyaluronate is over 255 to 1. In the second formulation, the weight ratio of GS to sodium hyaluronate is also very high (250 to 1). It is quite clear that the "invention" of Mr. Pierce within the provisional '838 Application was not solely a hyaluronic acid composition.

D. THE FIRST TIME MR. PIERCE DISCLOSED AN ORAL COMPOSITION/FORMULATION CONTAINING HA AS THE SOLE ACTIVE INGREDIENT WITHIN HIS PATENT PORTFOLIO WAS IN HIS NON-PROVISIONAL PATENT APPLICATION.

Mr. Pierce's '977 Application (issued as U.S. Patent No. 6,924,273) contains his first mention of an actual oral composition/formulation containing hyaluronic acid (HA) as the sole active ingredient. U.S. Patent No. 6,924,273 contains nineteen (19) separate formulations, the first formulation appearing within column 15 of the patent and the remaining eighteen (18) each labeled as an "EXAMPLE" within columns 17-21 of the patent. Out of the nineteen (19) referenced formulations, only **one**, namely EXAMPLE 1 appearing at the top of column 17, contains a composition/formulation wherein HA is the sole active ingredient. That particular formulation contains 0.144% sodium hyaluronate and no glucosamine sulfate or chondroitin sulfate. This particular formulation, namely the only formulation shown within U.S. Patent No. 6,924,273 containing HA as the sole active ingredient, first appeared within Mr. Pierce's non-provisional '977 Application and ***not*** within his provisional '838 Application.

E. BECAUSE PIERCE'S PROVISIONAL '838 APPLICATION DID NOT ENABLE AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE, AND BECAUSE THE PRIORITY DATE OF THE PRESENT APPLICATION PREDATES PIERCE'S NON-PROVISIONAL '977

APPLICATION, PIERCE'S NON-PROVISIONAL '977 APPLICATION IS NOT PRIOR ART WITH RESPECT TO THE PRESENT APPLICATION.

Pierce's provisional '838 Application did not enable an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate. Therefore, Pierce is not prior art with respect to the present Application. The parent application to the present Application, namely the '425 Application, was filed on May 18, 2001. Pierce's provisional application (the '838 Application) was filed on October 3, 2000, approximately 7 ½ months prior to the filing of the '425 Application. Pierce then converted the '838 Application to the '977 Application on October 2, 2001, approximately 4 ½ months after Leneau filed the parent application (the '425 Application) to the present Application (the '880 Application) claiming priority to the '425 Application.

Accordingly, and because the '977 Application was filed ***after*** the parent application (the '425 Application) for which the present Application (the '425 Application) claims priority, Pierce ***cannot*** be considered prior art with respect to such a composition, as Appellant/inventor Leneau first invented such a HA-only composition as first described in his '425 Application, filed approximately 4 ½ months ***earlier*** than Mr. Pierce's '977 Application. Thus, Appellant respectfully requests that the Examiner withdraw the rejection of the pending claims under 35 U.S.C. § 102(e) based upon Pierce and allow claims 1, 3-10, and 13 to proceed to allowance.

CONCLUSION

In summary, and as described above, the Examiner erred in rejecting the pending claims of the Application under 35 U.S.C. § 102(e) as being anticipated by Pierce, as Pierce does not suffice as 35 U.S.C. § 102(e) prior art because the disclosure of the provisional application for which Pierce claims priority did not sufficiently enable Pierce. Therefore, Appellant respectfully requests that the rejection of the pending claims under 35 U.S.C. § 102(e) based upon Pierce be withdrawn and that claims 1, 3-10, and 13 be allowed as patentable subject matter.

Respectfully submitted,

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